SUPREME COURT, U.

DEC 9 1974

No. 74-501

In the Supreme Court of the United States

OCTOBER TERM, 1974

WYETH LABORATORIES, a division of American Home Products Corporation, a Delaware corporation,

Petitioner,

vs.

EPIFANIO REYES, individually and as next friend of Anita Reyes, a minor,

Respondent.

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE IN SUPPORT OF PETITIONER'S PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BETTY JANE ANDERSON
535 North Dearborn
Chicago, Illinois 60610
(312) 751-6181
Attorney for the American Medical Association Amicus Curiae

Of Counsel
JAMES J. McNAMARA
535 North Dearborn
Chicago, Illinois 60610
(312) 751-6189

In the Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-501

WYETH LABORATORIES, a division of American Home Products Corporation, a Delaware corporation,

Petitioner,

vs.

EPIFANIO REYES, individually and as next friend of Anita Reyes, a minor,

Respondent.

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE

The American Medical Association respectfully moves for leave to file a brief *amicus curiae* in support of the petition for a writ of certiorari in this case. Petitioner's attorneys have consented to the filing of this brief.

Respectfully submitted,

/s/ Betty Jane Anderson
Betty Jane Anderson
Attorney for the American Medical Association Amicus Curiae
535 North Dearborn
Chicago, Illinois 60610
(312) 751-6181

Of Counsel
JAMES J. MCNAMARA
535 North Dearborn
Chicago, Illinois 60610
(312) 751-6189

In the Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-501

WYETH LABORATORIES, a division of American Home Products Corporation, a Delaware corporation,

Petitioner,

vs.

EPIFANIO REYES, individually and as next friend of Anita Reyes, a minor,

Respondent.

BRIEF AMICUS CURIAE IN SUPPORT OF PETITIONER'S PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

Interest of the Amicus Curiae

The American Medical Association is the national professional association of physicians. Founded in 1846, the Association has a current membership of 207,000 physicians and serves as the representative of the medical profession in the United States and its Territories.

The objects of the American Medical Association, as written into the Association's Constitution more than a century ago, are "to promote the science and art of medicine and the betterment of public health." The Purposes and Responsibilities of the American Medical Association

were further defined by the House of Delegates, the Policy-making body of the Association, in 1967, as follows:

"It is the responsibility of the American Medical Association, as the representative of the American medical profession, to continue to foster the advancement of medical science and the health of the American people.

"Its continuing purposes are to meet this responsibility through the following means:

"1. By encouraging the further development of medical knowledge, skills, techniques and drugs; and by maintaining the highest standards of practice and health care.

"2. By creating incentives to attract increasing numbers of capable people into medicine and the other health-care professions.

"3. By advancing and expanding the education of physicians and other groups in the health-care field.

"4. By motivating skilled physicians who have the art of teaching to apply themselves to developing new generations of excellent practitioners.

"5. By fostering programs that will encourage medical and health personnel to serve voluntarily in the areas of need for medical care.

"6. By developing techniques and practices that will moderate the costs of good medical and health care.

"7. By seeking out and fostering means of making all health-care facilities—physicians' offices, hospitals, laboratories, clinics and others—as efficient and economical as good medical practice and attention to human values will permit.

"8. By combining the utilization of the latest knowledge for prevention and treatment with the vital healing force of the physician's personal knowledge of and devotion to his patient.

"9. By maintaining the impetus of dedicated men and women in providing excellent health care by preserving the incentives and effectiveness of unshackled medical practice.

"10. By maintaining the highest level of ethics and professional standards among all members of the medical profession.

"11. By continuing to provide leadership and guidance to the medical profession of the world in meeting the health needs of changing populations."

The 1967 definition of the responsibilities of the American Medical Association in respect to the continuing advancement of the science and art of medicine and service to the public inculcates the principles upon which the Association agreed at its first meeting. The 1846 assembly acted on two issues requiring immediate attention: the establishment of a committee to promulgate ethical standards for the profession and a committee to concentrate on the elevation of standards of medical education that would assure the provision of quality medical services to the public.

At the annual meetings in 1847 and each year thereafter until federal and state health departments were active in epidemiology the House of Delegates received reports from its Committee on Practical Medicine on the "improvements effected in this country in the management of individual diseases" and "the progress of epidemics." In 1850, for example, the report included information on the sources of typhus fever and means suited to their ex-

tinction. By 1853, the House of Delegates was recommending that local societies appoint committees "to record the prevalence of epidemics or other diseases and the general state of health in their respective communities and to transmit said reports to the committees of the Society on Epidemics, through the state societies where they exist."

This concern that proper protection be afforded to the people of this country against the preventable diseases has continued throughout the history of the American Medical Association. As effective vaccines against communicable diseases have been developed and tested, the House of Delegates has consistently urged all physicians to support campaigns to motivate the public to protect the children of the country by proper immunization against the preventable diseases. The recent declining levels of immunization in pre-school children has been of particular concern to the Center for Disease Control and physicians. The AMA House of Delegates endorsed "Immunization Action Month" in 1973 and 1974 as one way to promote an increased immunization level for children against the preventable diseases.

Campaigns to promote the use of poliomyelitis vaccine by the public were endorsed by the House of Delegates in 1954, 1955 and 1957. In 1957, a national conference of state medical societies was held and poliomyelitis vaccine campaigns were organized by state and local medical societies. By 1964, 87.6 percent of children 1-4 years of age were immunized against polio. By 1972, the percentage had dropped to 62.9 and in 1973 to 61.2.

The importance of continuing efforts to assure a preventable disease-free population cannot be overemphasized. Public policy at the national and state levels supports mandatory immunization programs for pre-school children to

prevent polio, rubella, mumps, pertussis, tetanus and diphtheria. Immunization Action Month-1973 and 1974 represents a cooperative effort sponsored and coordinated by the Center for Disease Control, national medical and health organizations, a number of pharmaceutical companies and a number of voluntary action groups. The campaign urges physicians to review the immunization status of their patients, especially pre-school children, and to act to increase the immunization level of children against the preventable diseases.

Many pre-school children would not have the benefit of available vaccines if state and county public health departments are to find the conduct of such programs hampered by a lack of physician personnel to make individual medical judgments as to the advisability of administering one or more vaccines to pre-school children. This potential effect of the decision of the Fifth Circuit Court of Appeals in the *Reyes* case leads the American Medical Association to respectfully urge the Supreme Court to issue a writ of certiorari in this case of national significance and first impression.

Position Statement

It is the position of the American Medical Association that the nation's public health goal of complete protection of every child from paralytic poliomyelitis must be supported and encouraged to assure the nation-wide eradication of this infectious disease. This goal cannot be achieved unless primary immunization of infants and routine recall immunization are encouraged and made available through physicians' offices, clinics, public health departments and institutions. Only in this manner can the entire population be protected since such programs prevent exposure to infection from the chief spreaders of wild polioviruses, infants and pre-school children.

The extension of the tort doctrine of strict liability to the vaccines when used in public health programs does not serve the public interest and, in fact, may impede achievement of the public health goals of the country. The decision that the risks to the community of the spread of an infectious disease outweigh the statistically low danger of risk to individuals in the suspectible population group to whom the vaccine will be administered is made by the state. Texas made this decision for all pre-school age children. More specifically in this case, the decision was made on the basis of a possible community emergency stemming from the reported incidence of paralytic poliomyelitis in the area.

To argue that knowledge of a public health department's manner of administering routine and community-wide immunization programs imposes on a vaccine manufacturer a duty to either provide individual warnings to the ultimate consumer or to be responsible for seeing that the public health department provides such individual warnings overlooks the public policy considerations. Public policy in Texas, as in most states, mandates specified routine immunizations for all pre-school children. Public policy in Texas also encourages routine immunization for infants regardless of ability to pay, since the state health department provides vaccines to the local departments for administration to those unable to pay. The thrust of this public policy is the protection of the entire population as opposed to the preferences of an individual.

In public health immunization programs, a medical judgment is made on behalf of the community. The medical judgment would not be at variance from an individualized medical judgment, however, for any infant who had not received the vaccine prior to the determination that an epidemic threatened or existed in the community. The balancing of the risks against the benefits has been made by pedi-

atricians, public health physicians and physicians generally and it is based on a consensus of the opinion in the medical and scientific communities. Oral poliovirus vaccine is considered the vaccine of choice for community-wide vaccination programs and for routine and recall immunization in infancy and childhood because of its ease of administration, immunogenic effectiveness, protective capacity, potential for the eradication of poliomyelitis and statistically minimal risks. By 1966, the risk to adults of naturally occurring poliomyelitis had been reduced to such an extremely low level that continued immunization of adults was not recommended provided continued immunization of infants and pre-school children, the chief spreaders of wild polioviruses, was continued to protect susceptible adults indirectly by preventing virus circulation and therefore exposure to infection.

This case raises issues of national significance that have not been decided by the United States Supreme Court. The extension of the tort doctrine of strict liability to vaccines used in public health programs of national importance is an issue upon which the Supreme Court should rule for the guidance of the District and Circuit Courts of Appeal in the federal system. In the absence of such a ruling, disruption of immunization programs may have the undesirable effect of leaving large numbers of the citizens of the United States with inadequate protection against the spread of communicable diseases which can be prevented by vaccines and deprive a large class of indigent citizens of the only preventive health care available to them.

The extension of the tort doctrine of strict liability in this type of case is inappropriate. By making the manufacturer liable for sale of a vaccine considered unavoidably unsafe because of the miniscule risk associated with its

use and finding the product in "an unreasonably dangerous condition" when sold without specific warnings or individualized medical judgment that it is necessary and desirable for a particular patient flies in the face of the public health policy of this country. The court, in effect, is requiring the manufacturer either to give to the ultimate consumer the essential information for a valid, informed consent or arrange for a physician to be present and provide the elements necessary for a valid, informed consent. Public policy establishes that informed consent is not a requirement for vaccine administration. Consent has been supplied by statute and the federal and state public health department policies. Clarification of the applicability of public policy in public health immunization programs is necessary if the entire population is to receive the maximum protection possible from the spread of preventable communicable diseases.

Conclusion

Public policy considerations have been balanced consistently against possible injury to individuals by the courts in reaching decisions. Public policy favors public health immunization programs as necessary to serve the public interest by assuring preventable disease-free populations. The determination of public policy in health matters is based upon the consensus of scientific and medical experts in infectious diseases and preventive measures. Such determinations are not made without careful consideration of the risks to individuals and the resultant benefits to the population. The success of the public health immunization programs in this country can be shown by the eradication of smallpox, and the reduced incidence of

paralytic poliomyelitis, diphtheria, typhoid and other communicable diseases. This trend can be reversed in a short time if immunization programs are not encouraged and supported. The resultant loss of productive lives in this country would create an intolerable and unnecessary burden on society.

For the above reasons, the American Medical Association respectfully urges the Supreme Court to issue the writ of certiorari to review the judgment and opinion of the United States Court of Appeals for the Fifth Circuit.

Respectfully submitted,

/s/ Betty Jane Anderson
Betty Jane Anderson
Attorney for the American Medical Association
Amicus Curiae

November 25, 1974